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10/526,152	02/24/2005	Gianfranco Dè Paoli Ambrosi	71707	6495

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EXAMINER	
HOUGHTLING, RICHARD A	

ART UNIT	PAPER NUMBER
4133	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/526,152	DE PAOLI AMBROSI, GIANFRANCO	
	Examiner	Art Unit	
	Richard A. Houghtling, Ph.D.	4133	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other:_____.

DETAILED ACTION

1. Claims 1-19 are pending in the application received February 24, 2005; receipt of a Preliminary Amendment also filed February 24, 2005 is acknowledged and entered into the record and are examined on their merits, herein.

Foreign Priority

2. Applicants' claim to foreign priority under 35 U.S.C. 119(a)-(d) is acknowledged; a certified copy was filed February 24, 2005.

Information Disclosure Statements

3. Acknowledgement of receipt of one information disclosure statement filed by applicants on February 24, 2005; examiner entered disclosures into the record and references considered.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-2, 4, and 10 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 2 of U.S. Patent No. 7,169,811 (De Paoli Ambrosi) in view of Yu et al. (US Patent 5,686,489 found in applicant's IDS from February 24, 2005).

Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1 and 2 are drawn to a composition consisting essentially of as active ingredient, a mixture of ethyl linoleate (0.1% to 99.9% w/w) and triethyl citrate (99.9% to 0.1% w/w) of the composition. In the pending application, claim 1 is drawn to a composition for topical use for curing cutaneous pathologies, characterized in that it contains as an active ingredient triethyl citrate either pure or in combination with synergists, that is further limited by claim 2 to the amount of triethyl citrate present is 0.1 to 99.9% by weight. Each pending claim 4 or 10, further limit claims 1 or 2, respectively, as to a list that contains the synergists, of which **ethyl linoleate** is listed. As a result, in the pending application, the combination of triethyl citrate and ethyl linoleate is possible and therefore would result in a composition identical to that found in '811.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1 and 9 are drawn to a composition used to "cure" and a method of "curing" skin pathologies caused by a bacterial component.

Applicant claims 1 and 9 are drawn to "curing" cutaneous pathologies caused either indirectly or directly by bacterial infection, with the advantage that triethyl citrate does not promote bacterial resistance. Applicant discloses that triethyl citrate has been underappreciated for its role as an active ingredient for cosmetic or pharmaceutical purposes. Applicant further states that triethyl citrate may also be associated with appropriate synergists, that are defined by applicant and numerous agents are listed (see p. 3, lines 9-25 and p. 4, lines 1-4). However, applicant fails to disclose any details or provide any teachings as to which bacterial strains or which cutaneous diseases are susceptible to the effects of triethyl citrate (pure) or with any of the synergists. Without specific teachings as to all of the cutaneous pathologies that have etiology directly or

indirectly related to that from bacterial infections, it is unclear from applicant's disclosure how one is to achieve such success to "cure" all such forms of cutaneous pathologies. Additionally, applicant discloses no unexpected results, other than the mere statement that triethyl citrate impedes bacterial infections and advantageously does so without the result of increased bacterial resistance.

In order to cure all cutaneous pathologies caused by bacterial origin, applicant would need to first identify all of the known strains of bacteria which cause skin pathologies and further identify all possible skin pathologies—direct or indirectly affected by bacterial infections (p. 1, lines 8-11). It is unclear from applicant's disclosure how triethyl citrate, pure or in combination with the above-mentioned synergists, results in the curing of all cutaneous pathologies associated with bacterial infection to one of ordinary skill in the art. Furthermore from applicant's disclosure, a skilled artisan cannot envision all of the details and considerations necessary to be certain that every cutaneous pathology known or unknown to be caused by indirect or direct bacterial infection (by known or unknown strains of bacteria) is "cured" by triethyl citrate alone or in combination with the synergists. For example, to date, psoriasis, "a common chronic, scaly rash that affects people of all ages" (see DermNet NZ; p. 1, 1st ¶) that may be caused by bacterial infections such as, Streptococcal infections (DermNet NZ; p. 2, see "Infection" found under the heading, "What causes psoriasis?") cannot be cured (DermNet NZ; p. 3, see heading "Is there a cure?"). As such, it is unclear as to whether applicant was in possession of the invention at the time of

application. Therefore in such circumstances conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of identification of all susceptible bacterial strains and cutaneous pathologies positively affected by triethyl citrate treatment. Adequate written description requires more than a mere statement that is part of the invention and reference to a potential composition and method of using it as a cure. Applicant's disclosure does not reasonably convey to a skilled artisan that which is necessary for an artisan to make and use applicant's invention in the manner in which is claimed to result in a "cure of all cutaneous pathologies."

> an assertion that the claimed invention will be useful in "curing" the disease may require a significantly greater amount of evidentiary support to be considered credible by a person of ordinary skill in the art. In re Sichert, 566 F.2d 1154, 196 USPQ 209 (CCPA 1977); In re Jolles, 628 F.2d 1322, 206 USPQ 885 (CCPA 1980). See also Ex parte Ferguson, 117 USPQ 229 (Bd. Pat. App. & Inter. 1957).

For further information, refer to MPEP §804.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 4 and 6-19 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 4 and 10-11 the phrase "for example" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Regarding claims 4 and 10-11, the phrase "additional substances chosen ***between*** trans – retinal acid, retinol, retinaldehyde, tocopherol, ascorbic acid," it is unclear which additional substances are to be included in the list as the term ***between*** implies two substances, yet there are over 70 additional substances from which to choose.

Regarding claims 4, 9-11 the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Regarding claims 6-8 and 12-19, the terms "indirectly" and the phrase "bacterial component" are not defined within the specification, and thus the limits the claim scope which cannot be ascertained by one of ordinary skill in the art.

Furthermore claims 6-8 and 12-19 are "use" claims, as such, they are interpreted as process claims in which a composition containing triethyl citrate is used as a pharmaceutical substance at least for the treatment of cutaneous pathologies both directly and indirectly affected by infections of a bacterial origin (or bacterial

component), but, since these claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 101

7. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 6-8 and 12-19 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claims 1-19 are rejected under U.S.C. 101 because there is no credible utility for "curing" since skin conditions, such as psoriasis cannot be cured (see reference U, DermNet NZ article, pp. 1-4).

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-19 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Yu et al (US Patent 5,686,489 found in applicant's IDS from February 24, 2005).

Claims 1-5 and 10-11 are drawn to a composition for curing cutaneous pathologies by topical use characterized in that it contains as an active ingredient triethyl citrate either pure or in a combination with synergists; further limited to within particular ranges of weight percentages (claims 2-3); or the synergists to be combined (claims 4, 10-11) and the percentages by weight for the synergists (claim 5).

Applicant's claims 6-9 and 12-19 are drawn to a method (or "use" of composition) for the pharmaceutical or cosmetic use of a composition containing triethyl citrate (pure or in combination with synergists), formulated for topical application to skin for an effective amount of time for the treatment of cutaneous pathologies directly or indirectly affected by infections of bacterial origin

Yu et al. teaches compositions containing alpha hydroxyacid esters of which triethyl citrate is defined as a hydroxypolyacid ester (see group (d), col. 7, line 45 and col. 4, lines 35-65). The compositions taught by Yu et al. may contain one or more esters, as well as other topically applied, to the cutis or to membranes, agents that include **antimicrobial and anti-acne agents** (see col. 9, lines 34-52). Additionally, Yu et al. teaches pure triethyl citrate (100%) compositions as well as at or about many

other percentage ranges. In Examples 28-32, pure triethyl citrate (100%) is topically applied (col. 16, lines 43-67; col. 17, lines 1-29), whereas, additional examples illustrate other formulations using other percentages of triethyl citrate 18.3% (Examples 20 & 24), 30% (Example 1), 40% (Example 17), 50 % (Example 4) as well as ranges from at or about 1% to 5%, up to 100% at or about 20% range intervals (see col. 9, lines 63-67; col. 10, lines 1-9). Also, compositions taught by Yu et al. may be formulated for cosmetic or as an active agent (see col. 27, claim 38).

Yu et al. further teaches methods of treating aging related skin conditions comprising topically applying to skin, for a period of time sufficient to induce changes in the dermis, an alpha hydroxyacid ester, stereoisomer or racemate (claim 1) which is applied to intrinsically aged skin (claim 9), or additionally added to an alpha hydroxyacid or salt thereof (claim 20). Further comprising the method of claim 1, an additional step of topically applying a cosmetic or active agent (claim 25), which may be selected from many topical agents listed in claim 26 that includes many antibiotics (i.e. minocycline, nystatin, neomycin, kanamycin, erythromycin, tetracycline and clindamycin (col. 23, lines 29 and 34-35) and vitamin E (claim 26).

From the teachings of Yu et al., applicant's claims directed to a composition containing triethyl citrate either pure or in combination with synergists are clearly anticipated. Both Yu et al. and applicant's composition are applied topically (Yu et al., col. 10, lines 31-33; De Paoli Ambrosi, ¶9 last sentence) and are used for cutaneous

pathologies—aging and bacterial-induced skin ailments. The composition found in Yu et al. may be formulated by using different percentages of triethyl citrate as stated above and thus clearly anticipates applicant's claims 1-3 and 5. Likewise, the triethyl citrate composition taught by Yu et al. may also add to it, one or more topical agents listed (col. 9, lines 34-52 and col. 27, claim 32), many of which are also found in applicant's claims 4, 10 and 11, of which each depends from claims 1, 2 and 3, respectively.

The methods taught by Yu et al. using alpha hydroxyacid esters and/or alpha hydroxyacids or salts thereof, also clearly anticipate applicant's method (claim 9) or "use" claims 6-8 and 12-19. The methods taught by Yu et al. encompass both pharmaceutical and cosmetic substances (see col. 19, claim 1; col. 23, claim 25). When such a substance includes both the triethyl citrate and one of the antibiotic agents listed in claim 39 (see col. 27), the composition taught by Yu et al. also clearly anticipates applicant's "use" claims 12-19. Since the same composition was applied to the skin as claimed in Yu et al. then inherently the skin was treated for infections such as in claim 9, because the skin application reads on anyone's skin. Claim 9 does not require the skin to be of a particular type.

Conclusion

In conclusion, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard A. Houghtling, Ph.D. whose telephone number

is 571-272-9334. The examiner can normally be reached Monday to Thursday from 8:00 am - 5:00 pm. The examiner can also be reached on alternate Fridays (9 am – Noon).

The Group 1600 fax phone number where this application or proceeding is assigned is 571-273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Tech Center representative whose telephone number is (571)-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker, can be reached on 571-272-0911.

Richard A. Houghtling, Ph.D.

JEFFREY STUCKER
SUPERVISORY PATENT EXAMINER